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Patricia A Kammerer
Howrey Simon Arnold & White
750 Bering Drive
Houston, TX 77057-2198

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

14

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,480

Applicant(s)

Go (ds brough et al

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/17/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-4, 6-12, 14-21, 23, 26 is/are pending in the application.
- Of the above claim(s) 2-4, 6, 8 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 7, 9-12, 14-21, 23, 26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1638

Applicant's election with traverse of Group I and SEQ ID Nos: 1 and 2 in Paper No.15 is acknowledged. The traversal is on the ground(s) that the sequences are 83-97% similar to SEQ ID NO:1, that SEQ ID Nos: 9-10 are only 3' terminal sequences, and that a search of up to ten sequences is permitted. This is not found persuasive because SEQ ID NO:1 encodes a unique subclass of SBEII-1 enzyme, distinct from the SBEII-1 subclasses A-C of the other SEQ ID Nos., wherein each subclass is from a different genome, and wherein each subclass is encoded by different genes at different loci (see, e.g., pages 9, 15-16 and 20 of the specification). Furthermore, SEQ ID Nos: 9 and 10 are 3' regions of genes encoding enzymes of different subclasses than that of SEQ ID NO:1, and the 3' regions have more sequence divergence than the entire sequences (see, e.g., page 21 of the specification, second paragraph). Regarding the number of permissible sequences to be searched, the guidelines of "up to ten" were intended for small est sequences rather than large peptide-encoding sequences. In addition, resources at the Patent and Trademark Office have changed, such that a search of more than one coding sequence would constitute an undue burden. Finally, one sequence falls within the definition of "up to ten".

The requirement is still deemed proper and is therefore made FINAL.

Given the election of SEQ ID NO:1 encoding SEQ ID NO:2, claims 2-4, 6 and 8 of Group I, drawn to non-elected sequences, have also been withdrawn. Claims 1, 7, 9-12, 14-21, 23 and 26 are examined. Claims 7, 9-12, 14-21 and 23 will be examined to the extent that they read on the elected sequence.

Art Unit: 1638

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claims 9-12, 14-21 and 23 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim (i.e. claims 7, 9, 11-12, 14, 16-18, and 20 upon which claims 9, 11-12, 14, 16-18, 20-21 and 23 depend). See MPEP § 608.01(n). In the interests of compact prosecution, the claims have been examined. Such treatment does not relieve Applicants of the responsibility to respond to this objection.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 18-21 and 26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 26 are drawn to unpurified nucleotide sequences, and as such do not differ from those naturally occurring sequences found in whole wheat plants. The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. Claims 18-21 are drawn to progeny of transgenic plants, wherein said progeny might not retain the

Art Unit: 1638

transgene due to meiotic segregation, and so would be indistinguishable from naturally occurring plants.

Amendment of claims 1 and 26 to recite --isolated-- or --purified-- nucleotide sequences would obviate this portion of the rejection. Amendment of claims 18-21 to indicate that the progeny comprise the isolated nucleotide sequence would obviate this portion of the rejection.

See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9-12, 14-21, 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of "functional equivalent" which is defined in three different ways in the specification, so that it is unclear what is intended. On page 6, bottom paragraph, all SBE II-1 genes were deemed "functionally equivalent" to the maize SBE II b genes. On page 8, top paragraph, "functional equivalent" was defined as having at least 86% sequence similarity. On page 10, bottom paragraph, "functional equivalent" was defined as having at least 32% similarity.

Art Unit: 1638

Claim 1 is further indefinite in its recitation of “substantially” which fails to specify the degree of similarity. Furthermore, the recitation of a sequence which encodes “substantially” a particular sequence, or a “functional equivalent” thereof, introduces two levels of imprecision regarding the actual identity of the claimed nucleotide sequence.

Claim 7 is indefinite in its recitation of “any of the above sequences”. Since each of the above sequences appears in a different claim, it appears that claim 7 in fact is a multiply dependent claim. However, claim 7 fails to explicitly state that it depends upon other claims.

Claims 21 and 23 are indefinite in their recitation of “similar” and “equivalent” plants. It is unclear whether this refers to other plants of the same taxonomic class or family, such as maize or rice, or other plants which accumulate starch, such as potato; or whether this refers to untransformed plants of the same species, i.e. wheat.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9-12, 14-21 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any ill-defined “functional equivalent” of any nucleotide sequence from any source which “substantially” encodes SEQ ID NO:2, or any portion of a

Art Unit: 1638

nucleotide sequence which is only characterized by possessing at least 500 nucleotides of the “functional equivalent” of a nucleotide sequence “substantially” encoding SEQ ID NO:2 or which is 90% similar thereto; to plant cells and plants transformed therewith; and to methods of using the nucleotide sequences, portions, or equivalents to transform plants. In contrast, the specification only demonstrates plant transformation with a wheat sequence encoding the entire SEQ ID NO:2.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and

Art Unit: 1638

its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Art Unit: 1638

Claims 1, 7, 9-12, 14-21 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleotide sequences encoding the entire SEQ ID NO:2 from wheat and methods to transform plants therewith for alteration of starch properties, does not reasonably provide enablement for claims broadly drawn to any functional equivalent or fragment of said nucleotide sequence, or plant transformation therewith to alter any plant characteristic including starch content or composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any ill-defined "functional equivalent" of any nucleotide sequence from any source which "substantially" encodes SEQ ID NO:2, or any portion of a nucleotide sequence which is only characterized by possessing at least 500 nucleotides of the "functional equivalent" of the nucleotide sequence "substantially" encoding SEQ ID NO:2 or which is 90% similar thereto; to plant cells and plants transformed therewith; and to methods of using the nucleotide sequences, portions, or equivalents to transform plants to alter any plant characteristic (such as height or disease resistance) by altering the expression of any gene (claim 14). In contrast, the specification only demonstrates plant transformation with a wheat sequence encoding the entire SEQ ID NO:2 for alteration of starch content and/or composition.

The process of modifying starch accumulation in transgenic plants is particularly unpredictable. See Kossmann et al (1995; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate

Art Unit: 1638

content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph).

Since even homologous genes from the same organism were unable to alter gene activity when transformed back into that organism, as taught by Kossmann et al, it is unpredictable and unlikely that the instantly claimed starch branching enzyme genes would be able to alter the activity of unrelated genes in any plant or to alter non-starch characteristics (such as height or disease resistance) in any plant.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate from a multitude of sources a multitude of non-exemplified "functional equivalents" or "portions" of the exemplified wheat starch branching enzyme gene, to evaluate the ability of these non-exemplified sequences to cause any alteration in any characteristic (including starch content and/or composition) of any plant transformed therewith, or to evaluate the ability of the exemplified entire wheat starch branching enzyme gene to alter non-branching enzyme gene activity or non-starch characteristics in plants transformed therewith.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1638

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-12, 14-15, 17-18, 20-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/22703 (DU PONT).

The claims are broadly drawn to any nucleotide sequence encoding "substantially" any "functional equivalent" of an SBE II-1 enzyme (defined in the specification on page 6, bottom paragraph as functionally equivalent to the maize SBE II b enzyme), and methods of using the nucleotide sequence to transform a plant with a construct comprising said nucleotide sequence in sense or antisense orientation with respect to a promoter, for the alteration of starch properties.

DU PONT teaches plant transformation with an expression vector comprising the maize SBE II b gene (or 5' or 3' fragments thereof) in sense and antisense orientation with respect to a promoter, for alteration of starch produced by plant cells and plants transformed therewith (see, e.g., Abstract; pages 22-29, 31-38). The SBE II b gene has 59.8% overall similarity and 86.0% local similarity to SEQ ID NO:1 and encodes a protein with 72% overall and 90% local similarity to SEQ ID NO:2 (see Sequence Search results appended to Kossmann et al).

Claims 1, 9-12, 18-21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nair et al.

Claims 1 and 9-12 are drawn to nucleotide sequences functionally equivalent to a nucleotide sequence encoding "substantially" SEQ ID NO:2, and an expression vector and host cells transformed therewith. Claims 18-21 are drawn to untransformed progeny seeds, as

Art Unit: 1638

discussed above. Claims 1 and 26 are also drawn to an unpurified wheat gene, as discussed above.

Nair et al teach bacterial cells transformed with an expression vector comprising a wheat starch branching enzyme II gene which has 56.6% overall and 83.2% local similarity to SEQ ID NO:1 and which encodes a protein with 70.1% overall and 86.9% local similarity to SEQ ID NO:2 (see, e.g., page 153, Abstract; see also Sequence Search result appended to Kossmann et al).

Furthermore, Nair et al teach wheat plants which would inherently possess the wheat starch branching enzyme gene of SEQ ID NO:1 which encodes a wheat SBE II-1 enzyme, and which wheat plants would be indistinguishable from untransformed progeny of transformed plants (see, e.g., page 154, column 2, first full paragraph). Amendment of the claims to overcome the rejection under 35 USC 101 would overcome this portion of the art rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

Art Unit: 1638

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 14-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chibbar et al taken with each of WO 97/22703 (DU PONT) and Nair et al.

Claim 7 is broadly drawn to any portion of a nucleotide sequence "substantially" encoding a branching enzyme, wherein said portion is at least 500 base pairs and has at least 90% sequence similarity to the portion of the sequence from which it is derived, wherein said original sequence "substantially" encodes a "functional equivalent" of a wheat starch branching II-1 enzyme.

Claims 14-21 and 23 are broadly drawn to methods of transforming wheat plants with starch branching enzyme II genes which are functional equivalents of a gene encoding a wheat SBE II-1 in order to produce altered starch.

Chibbar et al teach wheat transformation with constructs comprising wheat SBE II genes in sense and antisense orientation with respect to a promoter, for the alteration of starch composition (see, e.g., page 249, Abstract; pages 250-254).

Chibbar et al do not teach wheat transformation with constructs comprising a gene substantially encoding a functional equivalent of a wheat SBE II-1 enzyme or a 500 base pair portion thereof with 90% sequence similarity thereto.

Art Unit: 1638

Each of DU PONT and Nair et al teach cereal transformation with constructs comprising a gene encoding a functional equivalent of a wheat SBE II-1 enzyme, for the production of starch with altered properties, as discussed above. Furthermore, DU PONT teaches plant transformation with 5' and 3' fragments, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of wheat transformation with starch branching enzyme II genes as taught by Chibbar et al, and to modify that method by incorporating the functional equivalents of the wheat starch branching II-1 gene as taught by each of DU PONT and Nair et al. Choice of particular gene or gene fragment encoding a particular starch branching enzyme would have been the optimization of process parameters.

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Allen et al, Accession No. ABK15494, disclosed in a U.S. Patent Application published 03 January 2002 as Published Application No. 20002002713, teach an isolated nucleotide sequence with 91.8% overall and 97.2% local similarity to SEQ ID NO:1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

June 2, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

